K103673

510(k) SUMMARY

AUG 18 2011

Contact Information

Donna T. Link
Director QA, RA and Compliance
TECHLAB®, Inc.
2001 Kraft Drive
Corporate Research Center
Blacksburg, VA 24060

Phone: 540-953-1664
FAX: 540-953-1665
Email: dlink@techlab.com

Date Prepared 09 August 2011

Product and Trade Name *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK™*

Classification 21 CFR 866.3220

Predicate Devices

- Merifluor™ *Cryptosporidium / Giardia* Kit
- *GIARDIA II*
- *CRYPTOSPORIDIUM II*

Intended Use

The *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK™* test is a rapid membrane enzyme immunoassay for the simultaneous qualitative detection and differentiation of *Giardia* cyst antigen and *Cryptosporidium* oocyst antigen in a single test device. It is intended for use with human fecal specimens from patients with gastrointestinal symptoms to aid in the diagnosis of *Giardia* and/or *Cryptosporidium* gastrointestinal infection. The test results should be considered in conjunction with the patient history.

Device Description

The *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK™* test is a rapid membrane immunoassay for the simultaneous detection of *Giardia* cyst antigen and *Cryptosporidium* oocyst antigen in a single test device. It is performed with a 25 to 30-minute total incubation time. The *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK™* test uses monoclonal and polyclonal antibodies to cell-surface antigens of the organisms. The device contains a *Reaction Window* with three vertical lines of immobilized antibodies. The *Giardia* test line ("Giar") contains mouse monoclonal antibodies against *Giardia*. The *Crypto* test line ("Cryp") contains mouse monoclonal antibodies against *Cryptosporidium*. The control line ("C") is a dotted line that contains anti-horseradish peroxidase (HRP) antibodies. The *Conjugate* consists of polyclonal antibodies coupled to horseradish peroxidase. To perform the test, the sample is added to a tube containing a mixture of *Diluent* and *Conjugate*. The diluted sample-conjugate mixture is added to the *Sample Well* and the device is allowed to incubate at room temperature for 15 minutes. During the incubation, cyst and/or oocyst antigens in the sample bind the antibody-peroxidase conjugates. The antigen-antibody-conjugate complexes migrate through a filter pad to a membrane where they are captured by the immobilized *Giardia* and/or *Cryptosporidium*-specific antibodies in the test lines. The *Reaction Window* is subsequently washed with *Wash Buffer*, followed by the addition of *Substrate*. After a 10 minute incubation period, the reaction is examined visually for the appearance of a vertical blue line on either side of the *Reaction Window*. A blue line indicates a positive test. A positive "control" reaction, indicated by a vertical dotted blue line under the "C" portion of the *Reaction Window*, confirms that the test is working properly and the results are valid.

Comparative Information of Equivalent Devices

Kit Name	510(k) Numbers	Intended Use	Format	Materials	Target Population
Microscopy	N/A	Direct detection of *Giardia* cysts and *Cryptosporidium* oocysts in fecal specimens	Microscopy	Various Stains	Persons suspected of having *Giardia* or *Cryptosporidium* infection
Merifluor™ *Cryptosporidium/ Giardia* Kit	K912408	Direct detection of *Giardia* cysts and *Cryptosporidium* oocysts in fecal specimens	Microscopy with Direct Fluorescent Antibody – Immuno-fluorescence (IFA)	Highly specific antibodies against *Giardia* and *Cryptosporidium*	Persons suspected of having *Giardia* or *Cryptosporidium* infection
GIARDIA II	K033274	Detection of *Giardia* cyst antigen in fecal specimens	ELISA	Highly specific antibodies against *Giardia*	Persons suspected of having *Giardia* infection
CRYPTOSPORIDIUM II	K052932	Detection of *Cryptosporidium* oocyst antigen in fecal specimens	ELISA	Highly specific antibodies against *Cryptosporidium*	Persons suspected of having *Cryptosporidium* infection

Summary of Performance Data
Clinical Performance

The performance of the *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK*™ test was evaluated at 3 geographically diverse sites. At Site #1 and Site #3 the performance of the *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK*™ test was compared to Microscopy (IFA) and included 220 fresh, 140 frozen, 216 preserved-formalin, and 215 preserved-SAF. At Site #1 and #2 the performance of the *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK*™ test was compared to two commercially available ELISAs (predicate devices for *Giardia* and *Cryptosporidium*) and included 349 fresh, 322 frozen, 36 preserved-formalin, and 142 preserved-SAF.

Performance as compared to Microscopy (IFA) - Combined Results for Study Sites #1 and #3:

For *Giardia* spp.
The following table shows a summary of the clinical performance of the *Giardia* portion of the *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK*™ test. The results show that the *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK*™ test exhibited a sensitivity of 98.9%, a specificity of 100%, and an overall correlation of 99.7% with Microscopy – IFA (considered the gold standard).

Combined Results - Clinical Performance Comparing the *Giardia* Line of the *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK*™ Test to Microscopy - IFA

N = 791	Microscopy - IFA *Giardia* positive	Microscopy - IFA *Giardia* negative
GIARDIA/CRYPTOSPORIDIUM QUIK CHEK ™ *Giardia* Line Positive	181	0
GIARDIA/CRYPTOSPORIDIUM QUIK CHEK ™ *Giardia* Line Negative	2	608

		95% Confidence Limits
Sensitivity	98.9%	95.7 – 99.8%
Specificity	100%	99.2 – 100%
Correlation	99.7%	99.7 – 99.7%

For *Cryptosporidium* spp.

The following table shows a summary of the clinical performance of the *Cryptosporidium* portion of the *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK*™ test. The results show that the *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK*™ test exhibited a sensitivity of 100%, a specificity of 99.8%, and an overall correlation of 99.9% with Microscopy – IFA (considered the gold standard).

Combined Results - Clinical Performance Comparing the *Cryptosporidium* Line of the *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK*™ Test to Microscopy - IFA

N = 791	Microscopy - IFA *Crypto.* positive	Microscopy - IFA *Crypto.* negative
GIARDIA/CRYPTOSPORIDIUM QUIK CHEK ™ *Cryptosporidium* Line Positive	140	1
GIARDIA/CRYPTOSPORIDIUM QUIK CHEK ™ *Cryptosporidium* Line Negative	0	650

		95% Confidence Limits
Sensitivity	100%	96.7 – 100%
Specificity	99.8%	99.0 – 100%
Correlation	99.9%	100 – 100%

Performance as Compared to Two Predicate Devices (commercially available devices for *Giardia* and *Cryptosporidium*) - Combined Results for Study Sites #1 and #2:

The combined results of our performance evaluations at Study Site #1 and #2 as compared to two commercially available ELISAs (predicate devices for *Giardia* and *Cryptosporidium*) exhibited a 99.1% agreement for *Giardia* positive specimens, a 99.7% agreement for *Giardia* negative specimens, with an overall agreement of 99.5%. The test exhibited a 99.2% agreement for *Cryptosporidium* positive specimens, 99.6% agreement for *Cryptosporidium* negative specimens, and an overall agreement of 99.5%.

GIARDIA/CRYPTOSPORIDIUM QUIK CHEK™ test *Giardia* Line versus the Commercial ELISA for *Giardia* Detection

N = 849	Commercial ELISA - *Giardia* positive	Commercial ELISA - *Giardia* negative
GIARDIA/CRYPTOSPORIDIUM QUIK CHEK ™ *Giardia* Line Positive	213	2
GIARDIA/CRYPTOSPORIDIUM QUIK CHEK ™ *Giardia* Line Negative	2	632

		95% Confidence Limits
Percent Positive Agreement	99.1%	96.3 – 99.8%
Percent Negative Agreement	99.7%	98.7 – 99.9%
Overall Percent Agreement	99.5%	99.5 – 99.5%

GIARDIA/CRYPTOSPORIDIUM QUIK CHEK™ test *Cryptosporidium* Line versus the Commercial ELISA for *Cryptosporidium* Detection

N = 849	Commercial ELISA - *Cryptosporidium* positive	Commercial ELISA - *Cryptosporidium* negative
GIARDIA/CRYPTOSPORIDIUM QUIK CHEK ™ *Cryptosporidium* Line Positive	130	3
GIARDIA/CRYPTOSPORIDIUM QUIK CHEK ™ *Cryptosporidium* Line Negative	1	715

		95% Confidence Limits
Percent Positive Agreement	99.2%	95.2 – 100%
Percent Negative Agreement	99.6%	98.7 – 99.9%
Overall Percent Agreement	99.5%	99.5 – 99.5%

Analytical Sensitivity

The analytical sensitivity of the device was determined by spiking purified *Giardia* cysts or *Cryptosporidium* oocysts quantified by immunofluorescent antibody microscopy (IFA) into negative human fecal specimens. The concentration of *Giardia* cysts and *Cryptosporidium* oocysts in fecal matrix where specimens were positive by the *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK* test 95% of the time were utilized to describe the assay limit-of-detection (LOD). Test results determined the LOD for the assay to be 6000 cysts/mL of feces for *Giardia* (equivalent to 133 cysts detected per test) and 6000 oocysts/mL feces for *Cryptosporidium* (equivalent to 133 oocysts detected per test). Because the *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK* test detects soluble antigen in fecal specimens in addition to cysts and oocysts, this LOD study represents an estimate of analytical sensitivity based on purified *Giardia* cysts and *Cryptosporidium* oocysts. Clinical specimens contain varying amounts of free antigen per *Giardia* cyst or *Cryptosporidium* oocyst.

Cross-Reactivity

The *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK*™ test was evaluated for cross-reactivity with the bacterial and viral strains listed below. None of the strains were shown to cross-react with the *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK*™ test.

Aeromonas hydrophila
Bacillus cereus
Bacillus subtilis
Bacteroides fragilis
Campylobacter coli
Campylobacter fetus
Campylobacter jejuni
Candida albicans
Clostridium bifermentans
Clostridium difficile (strain 630)
Enterococcus faecalis
Escherichia coli
Escherichia coli 0157:H7
Escherichia coli ETEC (enterotoxic)
Escherichia coli EPEC (enteropathogenic)
Escherichia coli EIEC (enteroinvasive)
Klebsiella pneumoniae
Salmonella typhimurium
Shigella dysenteriae
Shigella flexneri
Shigella sonnei
Staphylococcus aureus
Staphylococcus aureus (Cowan's)
Staphylococcus epidermidis
Vibrio parahaemolyticus
Yersinia enterocolitica

Human Adenovirus 1 and 3
Adenovirus, Type 2, 5, 40 and 41
Human Coxsackievirus B2, B3, and B4
Coxsackievirus B5
Human Coronavirus
Echovirus 11, 18, 33
Human Echovirus 9
Human paraechovirus 1 (Echovirus 22)
Enterovirus 68, 69
Human Enterovirus 70, 71
Human rotavirus

Additionally, the *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK*™ test was run on fecal specimens documented to be positive for other parasites by microscopy. No cross-reactivity was seen with the following organisms for either the *Giardia*-portion or the *Cryptosporidium*-portion of the test. Cross-reactivity to Astrovirus and Caliciviruses has not been established.

Ascaris lumbricoides eggs
Blastocystis hominis
Chilomastix mesnili
Cyclospora cayetanensis
Dientamoeba fragilis
Diphyllobothrium latum eggs
Endolimax nana
Entamoeba coli
Entamoeba hartmanni
Entamoeba histolytica/E. dispar
Hookworm eggs
Iodamoeba bütschlii
Trichuris trichiura eggs

INTERFERING SUBSTANCES (U.S. Formulations)

The following substances had no effect on positive or negative test results analyzed at the concentrations indicated: Hog gastric mucin (3.5% w/v), Human blood (40% v/v), Barium sulfate (5% w/v), Imodium® (5% v/v), Kaopectate® (5% v/v), Pepto-Bismol® (5% v/v), Steric/Palmitic Acid (40% w/v), Metronidazole (0.25% w/v), Vancomycin (0.25% w/v).

REPRODUCIBILITY

A total of 22 fecal specimens were pre-characterized by commercially available predicate devices. The samples included 6 *Giardia*-positive specimens (3 mid-range positives), 6 *Cryptosporidium*-positive specimens (3 low positives), and 4 *Giardia/Cryptosporidium*-positive specimens (2 of which were low *Giardia*-positives and 2 of which were low *Cryptosporidium*-positives), and 6 specimens negative for both parasites. All specimens were coded to prevent their identification during testing. Testing was performed at 3 sites. The samples were tested, twice a day over a 5-day period by multiple technicians at each site using 2 different kit lots. A positive and negative control was run with each panel of the masked samples. The results from each laboratory were subsequently submitted to TECHLAB®, Inc. and compared with in-house results. The results were consistent among the different locations, and exhibited a correlation of 100%. The positive specimens consistently tested positive and the negative specimens consistently tested negative at all sites using the *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK*™ test.

PRECISION – INTRA-ASSAY

For the determination of intra-assay performance, 6 positive fecal specimens (two positive for *Giardia*, two positive for *Cryptosporidium,* two positive for both *Giardia* and *Cryptosporidium*) and six negative fecal specimens were analyzed. Each specimen was assayed on 5 cassettes. All positives remained positive and all negatives remained negative.

PRECISION – INTER-ASSAY

For the determination of inter-assay performance, 16 positive fecal specimens (six positive for *Giardia*, six positive for *Cryptosporidium*, and four positive for both *Giardia* and *Cryptosporidium)* and six negative fecal specimens were assayed twice a day over a four-day period using the *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK*™ kit. All positives remained positive and all negatives remained negative.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

TechLab, Inc.
c/o Ms. Donna T. Link
Director, Quality Assurance, Regulatory & Compliance
2001 Kraft Drive
Blacksburg, VA 24060-6358

AUG 18 2011

Re: K103673
Trade/Device Name: The GIARDIA/CRYTOSPORIDIUM QUIK CHEK™
Regulation Number: 21 CFR§ 866.3220
Regulation Name: Qualitative membrane enzyme immunoassay
Regulatory Class: Class II
Product Code: MHJ, MHI
Dated: August 8, 2011
Received: August 8, 2011

Dear Ms. Link:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

2. INDICATIONS FOR USE

510(k) Number: K103673

Device Name: *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK™*

Indications For Use:

The *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK™* test is a rapid membrane enzyme immunoassay for the simultaneous qualitative detection and differentiation of *Giardia* cyst antigen and *Cryptosporidium* oocyst antigen in a single test device. It is intended for use with human fecal specimens from patients with gastrointestinal symptoms to aid in the diagnosis of *Giardia* and/or *Cryptosporidium* gastrointestinal infection. The test results should be considered in conjunction with the patient history.

FOR *IN VITRO* DIAGNOSTIC USE.

Prescription Use ___√____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K103673